UNITED STATES PATENT AND TRADEMARK OFFICE

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10/566,666	01/27/2006	Takashi Shirahata	1141/75776	5938

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EXAMINER
CONWAY, THOMAS A

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2010*.
2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.
　　4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-20* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
　　Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
　　Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
　　a)☒ All　b)☐ Some * c)☐ None of:
　　　1.☒ Certified copies of the priority documents have been received.
　　　2.☐ Certified copies of the priority documents have been received in Application No. _____.
　　　3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
　　* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO/SB/08)
　　Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
　　Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application
6)☐ Other: _____.

Examiner's responses to Applicant's remark

1.   Applicants' amendments filed on 6/1/2010 have been entered and made of

record.

2.   Applicants' arguments, see Remarks, filed 6/1/2010, with respect to the rejection

of claims 1, 3, 6, 11, 13 and 16 under 35 USC 102(b) and claims 2, 4, 5, 7, 9, 12, 14,

15, 17 and 19 under 35 USC 103(a) have been have been considered but are moot in

view of the new ground(s) of rejection.

3.   Applicant was silent with regards to previous rejections related to claims 8, 10, 18

and 20.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly
claiming the subject matter which the applicant regards as his invention.

4.   Claim 1 recites the limitation "reference value storing unit" in lines 13-14. There

is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or
> described as set forth in section 102 of this title, if the differences between the subject
> matter sought to be patented and the prior art are such that the subject matter as a
> whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability
> shall not be negatived by the manner in which the invention was made.

5.   This application currently names joint inventors. In considering patentability of

the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g)

prior art under 35 U.S.C. 103(a).

Claims 1, 3, 6, 11, 13 and 16 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Oosawa (US 7,616,789 B2) in view of Tatsuya et al. (JP

2002207992A).

6.   **Regarding claims 1 and 11**, Oosawa discloses a medical image diagnosis support device and method, comprising: a controller configured through a program of instructions, embodied in a non-transitory form in a computer readable medium, executable by the controller to include the following units (Fig. 12): an organ region setting unit for setting organ regions in medical images obtained by a medical imaging device (Col. 20, ln 7-15; See also Fig. 10 (P, P_c) - organ region is set to include regions that are similar between inputted image as well as stored normal images); a deformation calculating unit for calculating deformation from normal shapes of the organ regions set by the organ region setting unit in said medical images (Col 12, ln 33-39: P_{su} is the subtraction image which is the calculated degree of deformation from a normal shape); a reference storing unit for storing a reference value of the normal shapes of the organ regions (Col. 12, ln 20-22: P_c is a normal structure reference value); a lesion detecting unit for detecting existence of at least one lesion in an organ region from amongst the organ regions set by the organ region setting unit based on comparing the reference stored by the reference value storing unit with the deformation calculated by the deformation calculating unit (Col. 12, ln 40-43); and an informing unit for at least one of visually informing and auditorily informing the existence of the lesion in the organ region detected by the lesion detecting unit (Col. 12, ln 27-32: output means). However Oosawa fails to disclose where the deformation calculated and used in comparison is a set of geometric parameters related to deformation from normal shapes, and where the reference stored and compared is a set of geometric parameters related to normal shapes of organ regions.

Tatsuya teaches in the same field of endeavor, where comparison is made between calculated deformation set of geometric parameters and reference set of geometric parameters (¶ [0024-00280]: where geometric parameters of both the deformation calculation and reference of normal shapes include radii and thickness). Tatsuya discloses that lesion detection can be accomplished either by differencing images between a test template and a reference of a normal template OR by comparing geometric parameters of a test template and a reference template of a normal shape.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the known method of comparing geometric parameters of a test and reference template of Tatsuya's in place of Oosawa's known method to obtain predictable results of detecting a measurable anomaly indicative of a growth such as a lesion by using a nominal parameter representing a normal shape.

7.   **Regarding claims 3 and 13**, Oosawa and Tatsuya disclose the medical image diagnosis support device and method of claims 1 and 11. Oosawa further discloses wherein the reference value storing unit stores a plurality of templates according to the degree of deformation calculated by the deformation degree calculating unit (Col. 18, ln 63-66: each inputted image "P" corresponds to a normal reference image "P_c" which is approximately identical and has an associated subtraction image "P_{su}" or deformation degree - the images or templates can subsequently be stored in association with each other).

8.   **Regarding claims 6 and 16**, Oosawa and Tatsuya disclose the medical image

diagnosis support device and method of claims 1 and 11. Oosawa further discloses

wherein the informing unit informs the existence of the lesion visually by displaying the

lesion through colors or movement in displayed images (Col. 17, ln 33-51: pixel values

are displayed as black, white and variation of scale in-between, the color identifies

abnormal and normal tissue).

Claims 2, 4, 5, 7, 9, 12, 14, 15, 17 and 19 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Oosawa and Tatsuya in view of Greenberg et al. (US 6,301,498 B1:

"Greenberg").

9.   **Regarding claims 2 and 12**, while Oosawa and Tatsuya disclose the medical

image diagnosis support device and method of claims 1 and 11, their combination fails

to disclose a bifurcation detecting unit for detecting bifurcation into branches of an organ

region from amongst said organ regions ; a unit for creating a plurality of cross-sections

of the organ region diverged by the bifurcation detected by the bifurcation detecting unit;

and a distance calculating unit for calculating distances between or to said branches in

each of the plurality of cross-sections, and wherein the lesion detecting unit detects the

existence of the lesion in the organ region based on including said distances in said

deformation set of geometric parameters.

Greenberg discloses a bifurcation detecting unit for detecting bifurcation into branches of an organ region from amongst said organ regions (Col. 10, lines 17-21); a unit for creating a plurality of cross-sections of the organ region diverged by the bifurcation detected by the bifurcation detecting unit (Fig. 6d); and a distance calculating unit for calculating distances between or to said branches in each of the plurality of cross-sections (Col. 2, lines 36-42), and wherein the lesion detecting unit detects the existence of the lesion in the organ region based on including said distances in said deformation set of geometric parameters (Col. 3, lines 45-47).

Oosawa teaches that "the area of the region, the shape of the region, and the like" can be employed to determine an abnormal area (Col. 18, ln 10-12). Tatsuya also teaches where lumen radii and thickness are analyzed. Since lesions, stenosis and the like are often characterized by constriction or narrowing of a structure under inspection (specific to Greenberg's examination of arteries), examination of the geometric attributes of the suspect region would be an obvious endeavor (Greenberg, Col. 3, lines 18-25). Oosawa doesn't specifically mention using cross-sectional images since his invention dealt with chest images, but Tatsuya in the same field of endeavor, does rely on slice images (¶ [0024]) to compare reference images of normal shapes to shapes under test to discover lesion existence.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to include in the device and method as outlined by Oosawa and Tatsuya, a unit for detecting bifurcation into branches of an organ region from amongst said organ regions; a unit for creating a plurality of cross-sections of the

organ region diverged by the bifurcation detected by the bifurcation detecting unit; and a

distance calculating unit for calculating distances between or to said branches in each

of the plurality of cross-sections, and wherein the lesion detecting unit detects the

existence of the lesion in the organ region based on including said distances in said

deformation set of geometric parameters, as suggested by Greenberg, in order to

examine other internal structures other than the lungs.

10.   **Regarding claims 4 and 14**, while Oosawa and Tatsuya disclose the medical

image diagnosis support device and method of claims 1 and 11, their combination fails

to disclose wherein the deformation calculating unit includes: a cross-sectional image

calculating unit for calculating cross-sectional images that are orthogonal to axial

direction of an organ region from amongst said organ regions; and an extracting unit for

extracting a lumen and an exterior of the organ region from the cross-sectional images

calculated by the cross-sectional image calculating unit and calculating a deformation

set of parameters related to deformation of the lumen and the exterior of the organ

region extracted by the extracting unit.

Greenberg discloses a cross-sectional image calculating unit for calculating

cross-sectional images that are orthogonal to axial direction of an organ region from

amongst said organ regions (Fig. 5A); and an extracting unit for extracting the lumen

and an exterior of the organ region from the cross-sectional images calculated by the

cross-sectional image calculating unit (Fig. 5E); and calculating a deformation set of

parameters related to deformation of the lumen and the exterior of the organ region

extracted by the extracting unit (Col. 8, lines 40-54)

Therefore, for the same reasons as stated in the presentation of claims 2 and 12

(see above), it would have been obvious to one of ordinary skill in the art at the time the

invention was made, to include in the device and method as outlined by Oosawa and

Tatsuya, the unit as outlined by Greenberg, for calculating the cross-sectional images

that are orthogonal to axial direction of an organ region from amongst said organ

regions; and an extracting unit for extracting the lumen and the exterior of the organ

region from the cross-sectional images calculated by the cross-sectional image

calculating unit and calculating a deformation set of parameters related to deformation

of the lumen and the exterior of the organ region extracted by the extracting unit, in

order to examine other internal structures other than the lungs.

11.   **Regarding claims 5 and 15**, while Oosawa and Tatsuya disclose the medical

image diagnosis support device and method of claims 1 and 11, their combination fails

to disclose an extracting unit for extracting hollow viscera from an organ region amongst

said organ regions; a notable region setting unit for setting a notable region of the

hollow viscera extracted by the extracting unit; and an unit for creating cross-sectional

images of the hollow viscera extracted by the extracting unit based on the notable

region set by the notable region setting unit, and wherein the lesion detecting unit

detects the existence of the lesion of the organ region based on deformation of the

cross-sectional images of the hollow viscera.

Greenberg discloses an extracting unit for extracting hollow viscera from an organ region amongst said organ regions (Col. 5, lines 11-30); a notable region setting unit for setting a notable region of the hollow viscera extracted by the extracting unit (Col. 9, lines 19-24); and an unit for creating the cross-sectional images of the hollow viscera extracted by the extracting unit based on the notable region set by the notable region setting unit (Col. 9, lines 14-18), and wherein the lesion detecting unit detects the existence of the lesion of the organ region based on deformation of the cross-sectional images of the hollow viscera (Col. 19, lines 13-16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to include in the device and method as outlined by Oosawa and Tatsuya, a unit for extracting hollow viscera from an organ region amongst said organ regions; a notable region setting unit for setting a notable region of the hollow viscera extracted by the extracting unit; and an unit for creating the cross-sectional images of the hollow viscera extracted by the extracting unit based on the notable region set by the notable region setting unit, and wherein the lesion detecting unit detects the existence of the lesion of the organ region based on deformation of the cross-sectional images of the hollow viscera, as suggested by Greenberg, in order to facilitate the examination of other internal organs other than a lung.

12.   **Regarding claims 7 and 17**, Oosawa and Tatsuya disclose the medical image diagnosis support device and method according to claims 6 and 16. Oosawa also discloses a visual presentation that highlights the lesion candidate portions being

detected by the lesion detecting unit on the images (Col. 18, ln 30-32: "rectangle" or

"arrow"), but their combination fails to disclose wherein the informing unit displays

visual presentation by displaying the cross-sectional images of the organ regions, and

by highlighting lesion candidate portions detected by the lesion detecting unit on the

cross-sectional images.

Greenberg discloses wherein the informing unit displays visual presentation by

displaying the cross-sectional images of the organ regions, and by highlighting lesion

candidate portions detected by the lesion detecting unit on the cross-sectional images

(Claim 11: unit for expressing the X-ray intensity for each X-ray image as lumen

functions across an artery cross section).

Greenberg's teaching allows for discriminating the details of a region of

interest in such a way that would facilitate identification of lesions of other organs

other than the lungs. Lesions and stenosis of organs have geometric characteristics

that a cross-sectional image would present in a more obvious manner. Highlighting

the relevant areas in a cross-sectional image would even more so draw the attention

of an operator to the area of interest.

Therefore it would have been obvious to one of ordinary skill in the art at the

time of the invention to apply the teachings of Greenberg to Oosawa and Tatsuya in

order to facilitate identification by an operator of the existence of lesions in a cross-

sectional image.

13.   **Regarding claims 9 and 19**, Oosawa and Tatsuya disclose the medical image

diagnosis support device and method according to claims 1 and 11, but their

combination fails to disclose a cross-section extracting unit for extracting cross

sections from a feature quantity of a hollow viscera on the medical images obtained by

the medical imaging device; a physical quantity calculating unit for calculating a physical

quantity including radius, degree or circularity, and gravity point of the hollow viscera on

the hollow viscera cross-sections extracted by the extracting unit; an ROI calculating

unit for calculating a region of interest based on the physical quantity calculated by the

physical quantity calculating unit; a 3-dimensional image creating unit for creating 3-

dimensional images of the hollow viscera from the medical images including the cross

sections of the hollow viscera extracted by the cross section extracting unit within the

region of interest calculated by the ROI calculating unit; and an image displaying unit for

displaying the 3-dimensional images created by the 3-dimensional image creating unit.

Greenberg discloses a cross-section extracting unit for extracting cross

sections from a feature quantity of the hollow viscera on the medical images

obtained by the medical imaging device (Col.5, lines 30-33: Greenberg does this

using lumen functions.); a physical quantity calculating unit for calculating a physical

quantity including radius, degree of circularity, and gravity point of the

hollow viscera on the hollow viscera cross-sections extracted by the extracting

unit (Col. 3, lines 19-25: analysis of a cross-sectional area could produce radius,

degree of circularity as well as gravity point (understood to be a center point)) ; an

ROI calculating unit for calculating a region of interest based on the physical quantity

calculated by the physical quantity calculating unit (col. 3, lines 26-30); a 3-

dimensional image creating unit for creating 3-dimensional images of the hollow

viscera from the medical images including the cross sections of the hollow viscera

extracted by the cross section extracting unit within the region of interest being

calculated by the ROI calculating unit (Claim 1 : reconstructing the lumen functions

to create a three-dimensional image); and an image displaying unit for displaying the

3-dimensional images created by the 3-dimensional image creating unit (Abstract:

lines 7-8; see also Fig. 3A).

Analysis of organ and vessel shapes can indicate relevant conditions, such as

lesions and stenoses. Cross-sectioning areas of interest in order to develop

dimensional data with regards to an organ or vessel would facilitate an operator to

visually identify possible lesions or stenoses.

Therefore it would have been obvious to one of ordinary skill in the art at the

time of the invention to apply the teachings of Greenberg to Oosawa and Tatsuya in

order to calculate dimensional data of an area of interest by which an operator might

identify lesions or stenoses.

Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Oosawa and Tatsuya in view of Heilbrun et al. (U.S. Pub. No.: 20010039421

A1,"Heilbrun").

14.   **Regarding claims 8 and 18**, Oosawa and Tatsuya disclose the limitations of

claims 1 and 11. Oosawa further discloses informing the existence of a lesion to an

examiner (Col. 18, ln 30-32: "rectangle" or "arrow") but their combination fails to

disclose wherein the informing unit informs the existence of the lesion auditorily by

outputting it through voices and sounds, or a variance of the voices and sounds.

Heilbrun discloses informing auditorily by outputting it through voices and

sounds (Page 8, lines 6-10). While Heilbrun's notification is regarding the position of

the operative portion of an instrument relative to structures of interest, it is the goal

to notify the operator of relevant information that is important. In Heilbrun's invention,

the relevant information that needs to be related to the examiner is the position of

the operative portion of an instrument, while in Oosawa's invention; the relevant

information is the notification of the location of abnormal tissue. Giving auditory

notification to an operator of some type of event which is in the interest of the

operator to notice is an obvious method that is used in many arts. A voice alert is an

organized set of sounds relating to speech, therefore, the use of voice in itself is the

use of sound

Therefore it would have been obvious to one of ordinary skill in the art at the

time of the invention to include in the device and method of Oosawa and Tatsuya, the

step of informing auditorily by outputting it through voices and sounds as suggested by

Heilbrun, in order to more effectively draw the attention of an operator to a specific

area of relevance, such as the existence of a lesion.

Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Oosawa, Tatsuya and Greenberg in view of Knoplioch (U.S. Patent Number:

6643533, "Knoplioch").

15.   **Regarding claims 10 and 20**, while the combination of Oosawa, Tatsuya and

Greenberg disclose the limitations of claims 9 and 19, their combination fails to disclose

the limitations of claims 10 and 20.

Knoplioch discloses a center-line calculating unit for calculating a center line of

the hollow viscera based on the gravity point of the hollow viscera cross sections

calculated by the physical quantity calculating unit (Col. *6*, lines 31-34), wherein the

image display unit displays the center line calculated by the center-line calculating unit

together with the 3-dimensional images being created by the 3-dimensional image

creating unit (Col. 3, lines 22-24; with reference to Fig. 4 - See also: Col. 5, lines 18-

23). Knoplioch's teaching allows for geometrical display of organs under scrutiny with

reference to a centerline which would facilitate critical analysis of any objects of interest.

Abnormalities of organs and vessels are often easily noticed with reference to shape

and utilizing a reference plane or line such as a centerline, would facilitate determination

of abnormalities which might be considered relevant.

Therefore it would have been obvious to one of ordinary skill in the art at the time

of the invention to include in the method and device of Oosawa, Tatsuya and

Greenberg, a center-line calculating unit for calculating a center line of the hollow

viscera based on the gravity point of the hollow viscera cross sections calculated by the physical quantity calculating unit, wherein the image display unit displays the center line calculated by the center-line calculating unit together with the 3-dimensional images being created by the 3-dimensional image creating unit, as suggested by Knoplioch, in order to facilitate visual determination by an operator of displayed abnormalities which might be considered relevant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THOMAS A. CONWAY whose telephone number is (571)270-5851. The examiner can normally be reached on Monday through Friday 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bella Matthew can be reached on 571-272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

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USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas A. Conway/
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